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Erik Labergerie

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STURM & FIX LLP

206 SIXTH AVENUE

SUITE 1213

DES MOINES, IA 50309-4076

EXAMINER

JOYNES, ROBERT M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/01/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/819,496

Applicant(s)

LABERGERIE ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of applicants' Notice of Appeal filed on July 11, 2003 and Request for Continued Examination filed on September 10, 2003. Claims 1-31 have been cancelled. Claims 32- 47 have been added and remain pending.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-47 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,573,777 to Serpelloni *et al.*. Serpelloni *et al.* teach a relatively pure pulverulent mannitol, having a moderate and non-excessive friability, a low density, and a particle size of between 100 and 200 microns, wherein less than 30% of the particles have a size less than 75 microns (abstract). Serpelloni *et al.* also teach that the mannitol richness of their composition will be at least 90%, most preferentially greater than 98.5% (c 6, l 34-45). Serpelloni *et al.* also teach that the pulverulent mannitol can be formed through wet granulation (c 8, l 37-38). Lastly, Serpelloni *et al.* teach that the mannitol of their invention can be used as a sweetening agent, texturizing agent, or additive excipient or vehicle, in particular in the food and pharmaceutical fields. Therefore, the teachings of Serpelloni *et al.* anticipate the limitations of applicant's instant claims.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serpelloni *et al.*. Serpelloni *et al.* are described above as teaching a pulverulent mannitol composition, with moderate and non-excessive friability, low density, and less than 30% of particles with a size less than 75 microns. Serpelloni *et al.* do not disclose density in the same units as applicant, nor does Serpelloni *et al.* disclose a specific flow factor. However, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). It is the position of the examiner that one of ordinary skill in the art would look to the teachings of Serpelloni *et al.* in order to produce a pulverulent mannitol composition for use as a

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pharmaceutical excipient. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments filed July 23, 2002 have been fully considered but they are not persuasive. Applicants' argue that the packed bulk density for the mannitol of the instant claims differs from that of the prior art. In their response, applicants include a declaration attempting to show this difference and its criticality.

The Declaration is not commensurate in scope with the instant claims. The instant claims are drawn to a pulverulent mannitol having a particle size of 60 to 200 microns and a bulk packed density of between 0.65 and 0.85 g/mL. The Declaration is found to be persuasive but only for the limitations shown in the Declaration. More specifically, the Declaration is persuasive for a particle size range of 126 to 178 microns and a packed density of 0.71 or 0.72 g/mL. The difference between the density ranges claimed and those proven in the Declaration are even greater than the differences in packed density from the instant claims and the prior art. Therefore, it is the position of the Examiner that these differences are just as significant as the differences between the lower end of the range of the instant claims and the prior art.

Therefore, the rejections are maintained.


***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes  
Patent Examiner  
Art Unit 1615  
September 25, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600